61. The sheath of Claim 51, wherein said material is a polymeric material having fillers added thereto.

62. The sheath of Claim 51, wherein said material comprises glass.

63. The sheath of Claim 51, wherein said material comprises a metallic material.

64. The sheath of Claim 1, wherein said layer is a sulfonated or a fluorinated polymeric layer.

65. The sheath of Claim 1, wherein said layer is made from a carbide or nitride compound. --

REMARKS

This is a response to the Office Action dated 10/12/01. Claims 1-10 and 48-65 are pending in the application. With respect to Claims 11-15, Applicant respectfully requests reconsideration of withdrawal of these claims from further consideration. Claims 11-15 depend from Claim 1. Claim 1 is generic not only to Claims 1-10, but also to Claims 11-15. Applicant believes, as indicated below, that Claim 1 is patentably allowable over the cited references. Accordingly, because Claims 11-15 depend from Claim 1, Claims 11-15 should also be deemed allowable for at least the same reason.

Claims 1-10 have been rejected under 35 U.S.C. §112, second paragraph. Independent Claim 1 has been amended to cure the rejection. With respect to Claim 8, the acronym "DS" has been amended to "degree of substitution." "Degree of substitution" or "DS" is defined in the specification of the application as originally filed on page 11, line 4. Withdrawal of the rejection with respect to Claims 1 and 8 is respectfully requested. Claims 2-10 depend directly and indirectly from Claim 1 and accordingly should also be in allowable form.

Claims 1-3 have been rejected under 35 U.S.C. §102(b) as being anticipated by Tartaglia

et al. (US Patent No. 5,700,285). Tartaglia et al. teach a polymeric material attached to a stent. The polymeric material is attached to the stent and is used for the delivery of drugs. Tartaglia et al. disclose that "[t]he primary function of the sheet of polymeric material is to deliver therapeutic agents or drugs to help prevent thrombosis and/or restenosis" (col. 7, lines 25-27). Tartaglia et al. fail to teach a "sheath comprising a hollow body for removably covering ... [an] implantable medical device" and additionally a "layer that prevents said therapeutic substance from significantly absorbing into said body or said layer," as recited in Claim 1. The alleged "sheath" described in Tartaglia et al. is used to carry a therapeutic substance not to prevent a therapeutic substance from being significantly absorbed in the alleged "sheath." Accordingly, Claim 1 is patentably distinguishable over Tartaglia et al. Withdrawal of the rejection is respectfully requested. Claims 2 and 3 depend from Claim 1, and accordingly are distinguishable over Tartaglia et al. for at least the same reason.

Claims 1, 4, and 5 have been rejected under 35 U.S.C. §102(b) as being anticipated by Sahatjiian et al. (US Patent No. 5,306,246). Sahatjiian et al. describe an inflatable medical dilatation balloon made from, for example, commercially available polymers. The balloon is intended to have improved properties such as high compliance and low folded profile, high hoop stress, and high burst pressures. Applicant respectfully fails to see the relevance of this reference. The reference is merely directed to balloon material and not a "sheath comprising a hollow body for removably covering ... [an] implantable medical device." A sheath having "a layer that prevents said therapeutic substance from significantly absorbing into said body or said layer," of the sheath is also not disclosed. Accordingly, Claim 1 is patentably distinguishable over Sahatjian et al. Claims 4 and 5 depend from Claim 1 and are patentably distinguishable for at least the same reason.

Claims 1, 4, and 8 have been rejected under 35 U.S.C. §102(b) as being anticipated by Shee (US Patent No. 4,721,204). Shee teaches packaging for breakable glass ampules containing liquid chemicals (e.g., iodine). First, Shee does not teach a "sheath ... for removably covering ... [an] implantable medical device," as recited by Claim 1. Ampules are not "implantable medical devices," but are glass containers for holding chemicals. The chemicals contained in the ampules surely cannot be considered to be "implantable medical devices."

Second, the Examiner has referred to column 1 of Shee, in which the word "sheath" appears. In the background of the invention, Shee describes a conventional prep swab ampule which has an outer protective sheath. Shee recites, "[t]he purpose of the sheath is to permit compression between the fingers to break the glass capsule and release the liquid while protecting the fingers against being cut by the broken glass, and to contain the released liquid so that it can only be released through the permeable swab tip for application to a desired surface, such as the skin" (col. 1, lines 21-27). Shee fails to disclose a "sheath" that "prevents [a] therapeutic substance from significantly absorbing into said body or said layer" of the sheath as recited by Claim 1. Accordingly, Claims 1 is patentably distinguishable over Shee. Claims 4 and 8 depend from Claim 1 and are patentably distinguishable for at least the same reason.

Claims 1, 4-7, 9, and 10 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Sablotsky (U.S. Patent No. 4,585,452). The Examiner has found that the sheath claimed in Claim 1 would have been obvious in view of the device described by Sablotsky. The Applicant respectfully disagrees. As correctly pointed out by the Examiner, Sablotsky does teach a transdermal systemic dosage system. Sablotsky, however, fails to disclose a "sheath comprising a hollow body for removably covering ... [an] implantable medical device." In Fromsom v. Advance Offset Plate, 225 USPQ 26 (Fed. Cir. 1985), the court in considering prior art references under 35 U.S.C. § 103 observed that "the critical inquiry is

whether 'there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination." It is submitted that there is absolutely nothing in Sablotsky to suggest the use of a sheath, having a hollow body, to removably cover implantable medical devices such as stents and balloons. Applicant respectfully submits that changing the shape of an adhesive skin patch to a hollow sheath for covering implantable medical devices cannot reasonably be held to be a matter of mere design choice by one having ordinary skill in the art. The sheath is for covering a mechanical structure such as a stent or a balloon, while an adhesive patch is a tape for sticking to the skin. Applicant submits that Claim 1 is patentably distinguishable and not obvious over Sablotsky. Claim 4-7, 9 and 10 depend directly and indirectly from Claim 1 and are therefore patantably distinguishable for at least the same reason.

CONCLUSION

Claims 1-15 and 48-65 are pending in this application. Examination and allowance of the claims is respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned at (415) 954-0323.

Date: January 8, 2002

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as express mail in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231, on January 8, 2002.

Date: 1/8/02 By: _____
Name of person signing certification

Version With Markings To Show Changes Made

In the Claims:

The Italicized claims have not been amended and are provided for the Examiner's convenience.

1. (Amended) A sheath for an implantable medical device, said implantable medical device carrying a therapeutic substance which can be delivered to a subject, said sheath[,] comprising[:] a hollow body [capable of] for removably covering at least a portion of [a] said implantable medical device, [said device carries a therapeutic substance which can be delivered to a subject,] wherein said body comprises a layer that prevents said therapeutic substance from significantly absorbing into said body or said layer.

2. The sheath of Claim 1, wherein said device is a stent.

3. The sheath of Claim 1, wherein said device is a balloon.

4. The sheath of Claim 1, wherein said layer is made from a polymeric material selected from a group of polyolefins, polyurethanes, cellulosics, polyesters, polyamides, poly(hexamethylene isophthalamide/terephthalamide), poly(ethylene terephthalate-co-p-oxybenzoate), poly(hydroxy amide ethers), polyacrylates, polyacrylonitrile, acrylonitrile/styrene copolymer, rubber-modified acrylonitrile/acrylate copolymer, poly(methyl methacrylate), liquid crystal polymers, poly(phenylene sulfide), polystyrenes, polycarbonates, poly(vinyl alcohols), poly(ethylene-vinyl alcohol), epoxies composed of bisphenol A based diepoxides with amine cure, aliphatic polyketones, polysulfones, poly(ester-sulfone), poly(urethane-sulfone), poly(carbonate-sulfone),

poly(3-hydroxyoxetane), poly(amino ethers), gelatin, amylose, parylene-C, parylene-D, parylene-N, and mixture thereof.

5. The sheath of Claim 4, wherein said polyolefins are selected from a group of polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride), poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), and mixtures thereof.

6. The sheath of Claim 4, wherein said polyurethane has a glass transition temperature above a storage temperature.

7. The sheath of Claim 4, wherein said polyurethane has a non-polar soft segment, said non-polar soft segment is selected from the group of hydrocarbons, silicones, fluorosilicones, and mixtures thereof.

8. (Amended) The sheath of Claim 4, wherein said cellulosics are selected from the group of cellulose acetate having a [DS] degree of substitution greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, and mixtures thereof.

9. The sheath of Claim 4, wherein said polyesters are selected from a group of poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), and mixtures thereof.

10. The sheath of Claim 4, wherein said polyamides are selected from a group of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof.

11. (Amended) The sheath of Claim 1, wherein said layer is made from a polymeric material and [a predetermined amount of] fillers added to said polymeric material.

12. The sheath of Claim 1, wherein the layer is made from glass.

13. The sheath of Claim 1, wherein said layer is made from a metallic material.

14. (Amended) The sheath of Claim 1, wherein said layer comprises a therapeutic substance contacting surface[,] having a metallic substance disposed on said therapeutic substance contacting surface.

15. (Amended) The sheath of Claim 1, wherein said layer comprises a therapeutic substance contacting surface, said therapeutic substance contacting surface [has] having a coating of a main group element oxide formed thereon, said main group element oxide coating is selected from a group of silicon oxide and metal oxide.

Please add the following new claims:

-- 48. A sheath for packaging a medicated stent during transportation or storage of the medicated stent, the sheath comprising a hollow, tubular body in which the medicated stent can be inserted during transportation or storage of the medicated stent, the sheath being made from a material or an inner surface of the sheath being covered with a material which has an oxygen transmission rate of not more than about 200 cc/100 in^2, for 1 mil per 24 hours at 73° F, 75% relative humidity, and 1 atmosphere.

49. A sheath for packaging a medicated stent during transportation or storage of the medicated stent, the sheath comprising a hollow, tubular body in which the medicated stent can be inserted during transportation or storage of the medicated stent, the sheath being made from a material or an inner surface of the sheath being covered with a material which has a water vapor transmission rate of not more than 20 gm/100 in^2, for 1 mil per 24 hours at 100° F, 90% relative humidity, and 1 atmosphere.

50. A sheath for packaging a stent, the stent having a coating containing a

medication, the sheath comprising a hollow tubular body in which the stent can be removably inserted, wherein the body is made from a material or is lined with a material that prevents the medication from significantly diffusing out from the coating of the stent.

51. A sheath for covering an implantable medical device, said implantable medical device carrying a therapeutic substance which can be delivered to a subject, said sheath being made from a material that prevents said therapeutic substance from significantly absorbing into said sheath.

52. The sheath of Claim 51, wherein said device is a stent.

53. The sheath of Claim 51, wherein said device is a balloon.

54. The sheath of Claim 51, wherein said material is selected from a group of polyolefins, polyurethanes, cellulosics, polyesters, polyamides, poly(hexamethylene isophthalamide/terephthalamide), poly(ethylene terephthalate-co-p-oxybenzoate), poly(hydroxyamide ethers), polyacrylates, polyacrylonitrile, acrylonitrile/styrene copolymer, rubber-modified acrylonitrile/acrylate copolymer, poly(methyl methacrylate), liquid crystal polymers, poly(phenylene sulfide), polystyrenes, polycarbonates, poly(vinyl alcohols), poly(ethylene-vinyl alcohol), epoxies composed of bisphenol A based diepoxides with amine cure, aliphatic polyketones, polysulfones, poly(ester-sulfone), poly(urethane-sulfone), poly(carbonate-sulfone), poly(3-hydroxyoxetane), poly(amino ethers), gelatin, amylose, parylene-C, parylene-D, parylene-N, and mixture thereof.

55. The sheath of Claim 54, wherein said polyolefins are selected from a group of polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride), poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), and mixtures thereof.

56. The sheath of Claim 54, wherein said polyurethane has a glass transition temperature above a storage temperature.

57. The sheath of Claim 54, wherein said polyurethane has a non-polar soft segment, said non-polar soft segment is selected from the group of hydrocarbons, silicones, fluorosilicones, and mixtures thereof.

58. The sheath of Claim 54, wherein said cellulosics are selected from the group of cellulose acetate having a degree of substitution greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, and mixtures thereof.

59. The sheath of Claim 54, wherein said polyesters are selected from a group of poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), and mixtures thereof.

60. The sheath of Claim 54, wherein said polyamides are selected from a group of nylon-6, nylon-6,6, nylon-6,9, nylon-6,10, aromatic nylon, and mixtures thereof.

61. The sheath of Claim 51, wherein said material is a polymeric material having fillers added thereto.

62. The sheath of Claim 51, wherein said material comprises glass.

63. The sheath of Claim 51, wherein said material comprises a metallic material.

64. The sheath of Claim 1, wherein said layer is a sulfonated or fluorinated polymeric layer.

65. The sheath of Claim 1, wherein said layer is made from a carbide or nitride compound. --